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Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

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[Continued on next page]

(54) Title: MULTILAYER TABLETS CONTAINING THIAZOLIDINEDIONE AND BIGUANIDES AND METHODS FOR PRODUCING THEM

(57) **Abstract:** A novel patient-convenient, cost effective pharmaceutical composition, comprising of thiazolidinediones and biguanide for controlling hyperglycemia manufactured as multilayer tablet and its process of manufacturing, for immediate release of thiazolidinediones or thiazolidinediones and biguanide and prolonged release of the biguanide only, the tablet comprising of minimum two layers wherein one outer layer comprises of a mixture of excipients and thiazolidinediones or thiazolidinediones and biguanide allowing immediate release of thiazolidinediones or thiazolidinediones and biguanide respectively and the other layer arranged in contact with the immediate release layer which comprises of a novel composition of excipients and a minimum one or more non-biodegradable, inert polymer(s) and the biguanide allowing pH independent prolonged release of the biguanide up to a period of 8-12 hours. The tablets are for once a day dosing. The tablets may optionally be film coated or enrobed by soft gelatin ribbons for additional protection against oxidation, photodegradation, identification, ease of swallowing, taste masking and for aesthetic appeal without altering the dissolution profile.

WO 03/105809 A1